

REMARKS

By this amendment, the subject matter of claims 2 and 3 is incorporated into claim 1. Claims 2, 3 and 21-26 are canceled. Claims 1 and 6-12 are pending. No issue of new matter arises. Entry of this amendment is proper because the amendment only cancels claims thereby expediting prosecution and raises no new issues.

Rejections under 35 U.S.C. §112, first paragraph

Claims 21-26 are canceled. Rejections relating to these claims are thereby mooted and are not further discussed.

Rejection of claims 1-3 and 6-12 was maintained under 35 U.S.C. §112, first paragraph as allegedly failing to meet written description and enablement requirements. Applicant respectfully traverses these rejections. Subject matter previously recited in claims 2 and 3 is now incorporated into claim 1.

Written Description

The Office Action asserts that the claimed genus includes substantial variation within the genus. The Office Action comments “one must describe a sufficient variety of species to reflect the variation within the genus.” Applicant respectfully submits that when a component is known in the art the knowledge and skill embodied in the art must be considered. Each component of the claimed nucleic acid molecule is well-known in the art. Thus the claimed molecule is adequately described to apprise the skilled artisan that Applicant was in possession of the claimed invention.

For example, the Office Action acknowledges that the skilled artisan would or should be aware of a large variety of signal sequences that make up the genus of signal sequences. Since the genus is known in the art to encompass many species, the skilled artisan would have understood the present inventor to have been in possession of the invention as claimed including claims including the concept of a generic signal sequence as part of the nucleic acid construct. The concept of a signal sequence is not claimed by Applicant. A signal sequence as known in the art is merely a component of the claimed structure. While some representative species of the recited structural component are embodied in the examples of the specification, there is no requirement in patent law that every possible embodiment of each claim element be shown in an example or for that matter even listed in the application. Knowledge and skill in the art are expected to be used by the skilled artisan for understanding the invention. Accordingly, Applicant’s use of the generality “signal sequence”, especially with one or more examples would have indicated to the skilled artisan that Applicant possessed the invention as claimed and thus the written description requirement was met. The Office Action has made no showing as to why

any particular signal sequence would have been considered to be outside the generic description provided in the specification. No evidence or argument is advanced in the Office Action as to why the disclosed species should not be considered representative of the genus of claimed molecules. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Enablement

The Office Action beginning at page 5, last paragraph, discusses reasons for maintaining this rejection. The Office Action ascribes a “make and test position” to Applicant and states that this “make and test position” is inconsistent with Fisher. Applicant respectfully submits that the invention as claimed does not require the “make and test position” ascribed to it. The present invention provides a structure that improves yield of a secreted protein. No claim is directed to an attempt “to test all the different type nucleic acid molecule encompassed by the claimed invention”. Office Action, page 6, lines 14 and 15. Since the scope of the claims does not, as alleged in the Office Action, include testing all the molecules, the rejection is clearly improper and should be withdrawn.

The Office Action speaks to unpredictability relating to a number of nucleic acid molecules. Applicant respectfully submits that the concept of unpredictability is not operative here. The process of transcription and translation to express a polypeptide or protein is well known in the art. Although there are multiple codons encoding some amino acids, the performance of each codon and its interaction with a corresponding tRNA is well known in the art and thus predictable. Although a large number of nucleic acid molecules can be made, the protein expressed is predictable. Expressing a protein is well-known in the art and thus clearly enabled. Therefore merely citing a large number of possible embodiments cannot properly be relied upon as suggesting a need for undue experimentation.

The present genus of molecules recited in claim 1 includes a combination of nucleotides. The combination includes several functional component regions. Each component region is defined in structure and function.

Indeed a large number of combinations can be made within the scope of the invention. But each component is either optional or well known in the art. Making and using nucleic acids is a well-developed art and no longer can be said to be unpredictable. Splicing or connecting nucleic acids together is well-known in the art. Thus making is clearly enabled. The claims of the present invention do not include a requirement “to test all the different type nucleic acid molecule encompassed by the claimed invention”. Accordingly, no issue of undue experimentation can be said to arise. Without a properly derived conclusion that undue

experimentation would have been required to practice the claimed invention, a lack of enablement rejection under 35 U.S.C. §112, first paragraph is improper.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Provisional Double Patenting Rejections

Claim 1 was provisionally rejected under a judicially created concept of double patenting. Applicant will take appropriate action if and when indication of allowable claimed subject matter requires amendment or other action in this or one of the conflicted applications.

Conclusion

Entry of the amendments is proper under 37 C.F.R. §1.116 because the amendments place the application in condition for allowance; do not raise new issues requiring further search and/or consideration; comply with a suggestion made in the Office Action; and/or place the application in better condition for appeal should an appeal be necessary.

In view of the above amendments and remarks, Applicant respectfully submits that the application is now in condition for allowance and requests prompt issuance of a Notice of Allowance. Should the Examiner believe that anything further is desirable that might put the application in even better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

The Commissioner is authorized to charge any additional fees or credit any overpayment necessitated by this response to Deposit Account No. 18-1982.

Respectfully submitted,



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